

S/N 09/880,576

PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Alferness et al.	Examiner	B. Szmaj
Serial No.:	09/880,576	Group Art Unit:	3736
Filed:	June 13, 2001	Docket No.:	11998.5USC2
Title:	CARDIAC DISEASE TREATMENT AND DEVICE		

DECLARATION OF EDWARD SHAPLAND AND SPENCER KUBO UNDER 37
CFR § 1.132

1. I Edward Shapland declare and state as follows. I have credentials.

2. I Spencer Kubo declare and state as follows. I have credentials.

3. We have read and are familiar with the office action mailed from the United States Patent and Trademark Office on September 11, 2002 and the specification of the above referenced application. We have also considered the Examiner's rejection of claims 18-31 under 35 U.S.C. § 112, first-paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. We respectfully disagree with the Examiner's opinion on this issue and offer the following comments related thereto.

4. Cardiac pacing is a standard therapy to treat various disturbances of the heart's electrical conduction system. This includes pacing of the heart to treat heart failure. The pacing leads conduct the electrical stimulation from the pacemaker to the heart. The stimulating tip of the lead can be placed within the main chambers of the heart or on the outer surface of the heart's main pumping chamber. The configuration and use of such systems were of general knowledge at the time of this invention, (ref. Electrical Therapy for Cardiac Arrhythmias, edited by S. Saksena and N. Goldschlager, W.B. Saunders Company, 1990).

5. The use of a device, positioned around the heart to constrain circumferential expansion, was known prior to this invention based on published patents and research findings.

6. As a result of reading page 13 (of the above identified patent application), one skilled in the art would know how to attach a pacing lead and pace the heart in conjunction with cardiac support jacket. The open cell, knit construction of the described jacket would provide adequate access for the pacemaker lead. It would overcome any potential issues associated with the fact that the jacket material is an electrical insulator. Standard pacing systems could be used without the need for special pacing leads. In addition, standard pacemaker features, such as output settings, sensing levels, etc. would be adequate to pace the heart in conjunction with a support device as outlined on page 13.

7. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: _____

By: **Edward Shapland**

Date: _____

By: **Spencer Kubo**

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Document Transmitted:**Message:**

Exmr. Szmal -
Here is the draft declaration. I look forward
to discussing it with you on Monday.
Thanks - Anna.

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